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Submitted via <http://www.regulations.gov>

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program

Dear Administrator Brooks-LaSure,

The Society for Healthcare Epidemiology of America (SHEA) appreciates the opportunity to submit comments on the on the Centers for Medicare and Medicaid Services' (CMS) Fiscal Year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System (LTCH PPS) proposed rule (herein referred to as "proposed rule").

SHEA represents more than 2,000 physicians and other healthcare professionals globally with expertise in healthcare epidemiology, infection prevention and antibiotic stewardship. SHEA is dedicated to advancing the science and practice of healthcare epidemiology and preventing and controlling morbidity, mortality and the cost of care linked to healthcare-associated infections (HAIs) and antibiotic resistance.

SHEA respectfully submits comments on the following sections of the proposed rule:

- **Hospital Readmissions Reduction Program (HRRP);**
- **Hospital Value-Based Purchasing (VBP) Program;**
- **Hospital-Acquired Condition (HAC) Reduction Program;**
- **Hospital Inpatient Quality Reporting (IQR) Program;**

- **PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;**
- **Long-Term Care Hospital Quality Reporting Program (LTCH QRP);**
- **Proposed COVID-19 Vaccination Coverage Among HCP Measure affecting FY 2023 payment determination in the Hospital IQR Program, PCHQR Program, and LTCH QRP**
- **Closing the Health Equity Gap in CMS Hospital Quality Programs – Request For Information; and the**
- **Advancing to Digital Quality Measurement and the Use of Fast Healthcare – Request for Information.**

Thank you in advance for your consideration of our comments. Please do not hesitate to reach out with questions to Lynne Batshon, Director of Policy and Practice, at (703) 684-0761 or ibatshon@shea-online.org.

Sincerely,



Mary K. Hayden MD, FIDSA, FSHEA
President, SHEA

Hospital Readmissions Reduction Program (HRRP)

Proposals to Address the Impact of COVID-19 on Current Hospital Readmissions Reduction Program Measures

- Cross-Program Measure Suppression Policy Proposal (Applicable to HRRP, Hospital VBP, HAC Reduction Program and Other Value-Based Purchasing Programs) for Duration of COVID-19 PHE

On pp. 25460, CMS states:

“...[W]e are proposing to adopt a policy for the duration of the PHE for COVID-19 that would enable us to suppress the use of quality measures...if we determine that circumstances caused by the COVID-19 PHE have affected those measures and [their associated calculations] significantly.”

Further, on p. 25461, CMS delineates the provider quality improvement programs to which this broader measure suppression policy would apply:

“...[W]e developed a number of Measure Suppression Factors that we believe should guide our determination of whether to propose to suppress a Hospital Readmissions Reduction Program measure for one or more program years that overlap with the PHE for COVID-19. We are proposing to adopt these Measure Suppression Factors for use in the Hospital Readmissions Reduction Program, and for consistency, the following value based purchasing programs: Hospital

VBP Program, HAC Reduction Program, Skilled Nursing Facility Value-Based Purchasing Program, and End-Stage Renal Disease Quality Incentive Program.”

Finally, on p. 25461, CMS proposes the following Measure Suppression Factors to evaluate measures across programs (i.e., to determine whether the measure suppression policy should apply):

- (1) Significant deviation in national performance on the measure during the PHE for COVID-19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years;*
- (2) Clinical proximity of the measure’s focus to the relevant disease, pathogen, or health impacts of the PHE for COVID-19;*
- (3) Rapid or unprecedented changes in: (iii) Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or (iv) the generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin;*
- (4) Significant national shortages or rapid or unprecedented changes in: (i) Healthcare personnel; (ii) medical supplies, equipment, or diagnostic tools or materials; or (iii) patient case volumes or facility-level case mix.*

SHEA appreciates CMS’ recognition of the significant and ongoing effects of the COVID-19 pandemic on the provision of health care and the need for flexibility in quality programs to account for the impact of these conditions that are outside of providers’ control. We support CMS’ proposal to assess measures in hospital VBP programs using the four proposed criteria – i.e., Measure Suppression Factors – delineated in the proposed rule. We believe that doing so will help ensure consistency in measure evaluations in the HRRP and other value-based purchasing programs.

- Proposal to Suppress the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the FY 2023 Program Year

On p. 25462, CMS states:

“In this proposed rule, we are proposing to suppress temporarily the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the FY 2023 program year under proposed Measure Suppression Factor 2, clinical proximity of the measure’s focus to the relevant disease or pathogen, particularly for a novel disease or pathogen of unknown origin, due to the COVID-19 PHE.”

Given the unprecedented COVID-19 PHE circumstances and impact on measure evaluation, SHEA supports CMS’ proposal to suppress the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) for the FY 2023 program year. We furthermore appreciate CMS’ provision of confidential feedback reports to hospitals to keep them apprised of any changes in performance rates that are observed and to inform quality improvement activities, though it is unclear why suppressed measures would be publicly reported.

- Technical Measure Specification Update to Exclude COVID-19 Diagnosed Patients from All Other Condition/Procedure-Specific Readmission Measures Beginning with FY 2023

On p. 25464, CMS states:

“Due to the impact of the COVID-19 PHE on the measures used in the Hospital Readmissions Reduction Program...we are updating these five condition/procedure-specific readmission measures to exclude COVID-19 diagnosed patients from the measure denominators [beginning in FY 2023]. This technical update will modify these five condition/procedure-specific readmission measures to exclude certain ICD-10 Codes that represent patients with a secondary diagnosis of COVID-19 from the measure denominators, but will retain the measures in the program.”

[The five condition/procedure-specific readmission measures are delineated on p. 25460, namely: (1) the Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505); (2) the Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515); (3) the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891); (4) the Hospital 30-Day, All-Cause, Risk Standardized Readmission Rate (RSRR) Following Heart Failure Hospitalization (NQF #0330); and (5) the Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551)].

SHEA supports CMS’ proposal to update the technical specifications for the five condition/procedure-specific readmission measures to exclude COVID-19 diagnosed patients from the measure denominators beginning in FY 2023. We concur with CMS’ reasoning that retaining these measures in the program, while excluding COVID-19 patients from the measure denominator, will continue to provide important information that is vital to enhancing quality of care measured under the HRRP. Prior to finalizing this proposal, we respectfully request that CMS provide additional details regarding the specific ICD-10 codes that represent patients with a secondary diagnosis of COVID-19 from the measure denominators.

- Request for Public Comment on Possible Future Stratification of Results by Race and Ethnicity for Condition/Procedure-Specific Readmission Measures

On p. 25468, CMS invites public comment on the following:

- (1) The possibility of confidentially reporting in HSRs [Hospital Specific Reports] stratified results using indirectly estimated race and ethnicity in addition to the currently reported results stratified using dual eligibility, for the six condition/procedure-specific readmission measures, and by expansion of standardized data collection to additional social factors, such as language preference and disability status;*
- (2) The possibility of publicly reporting stratified results using both indirectly estimated race and ethnicity, and dual eligibility, publicly on Care Compare, after at least one year of confidential reporting and further rulemaking, for the six condition/procedure-specific measures; and*

- (3) *On possible mechanisms of incorporating other demographic characteristics into analysis that address and advance health equity, such as the potential to include administrative and self-reported data to measure co-occurring disability status.*

SHEA enthusiastically supports CMS' goal of improving health care outcomes for Medicare beneficiaries through intentional quality improvement activities aimed at reducing health inequities. We appreciate the complementary methods CMS delineated in the rule to calculate disparities in readmission measures, namely the Within-Hospital and Across Hospital disparity methods. We look forward to working with CMS on this important undertaking as it moves toward promulgating specific proposals in future rulemaking.

Hospital Value-Based Purchasing (VBP) Program

Proposed Flexibilities for the Hospital VBP Program in Response to the Public Health Emergency (PHE) Due to COVID-19

- Cross-Program Measure Suppression Policy Proposal (Applicable to HRRP, Hospital VBP, HAC Reduction Program and Other Value-Based Purchasing Programs) for Duration of COVID-19 PHE

On p. 25470-25471, CMS states:

"...[W]e are proposing to adopt a policy for the duration of the PHE for COVID-19 that would enable us to suppress the use of data for a number of measures if we determine that circumstances caused by the COVID-19 PHE have affected those measures and the resulting Total Performance Scores significantly." CMS goes to outline the proposed Measure Suppression Factors, applicable to the Hospital VBP Program and other value-based purchasing programs (e.g., HRRP, HAC Reduction Program etc.).

Please refer to SHEA's comments regarding this broader CMS proposal in the HRRP section of our comment letter.

- Proposals to Suppress Specific Measures for the FY 2022 Program Year: The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Measure (NQF #0166); Medicare Spending Per Beneficiary (MSPB) (NQF #2158); and Five Hospital Acquired Infection (HAI) Measures

On p. 25470, CMS states:

"We are also proposing...to suppress all of the measures in the Person and Community Engagement, Safety, and Efficiency and Cost Reduction Domains for the FY 2022 program year because we have determined that circumstances caused by the COVID-19 PHE have affected those measures significantly, and to adopt a special scoring and payment rule for that program year."

Specifically, on p. 25472, CMS delineates the measures corresponding to the above domains that it proposes to suppress for the FY 2022 program year:

- *HCAHPS (NQF #0166)*

- *MSPB – Hospital (NQF #2158)*
- *National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)*
- *NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)*
- *American College of Surgeons – CDC Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753)*
- *NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcomes Measure (NQF #1716)*
- *NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717)*

SHEA supports CMS’ proposal to suppress the HCAHPS, MSPB, and five HAI Safety Measures (CLAUTI, CLASBI, Colon and Hysterectomy SSI, MRSI, and CDI) for the FY 2022 program year based on the first criterion or Measure Suppression Factor. We appreciate that hospitals would continue to report the measure data to CDC and CMS to ensure ongoing quality improvement monitoring. Moreover, through this process, we urge CMS to assess whether potential variability in reporting, versus variability in actual performance, could be driving variability in HAI rates.

- Proposal to Suppress Only One Measure for the FY 2023 Program Year: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT-30-PN) (NQF #0468)

On pp. 25470-25471, CMS states:

“For the FY 2023 program year, we are proposing to suppress only one measure, MORT-30-PN because we have determined that circumstances caused by the COVID-19 PHE have affected this measure significantly, but we are not proposing to adopt a special scoring and payment rule for that program year...The FY 2024 and FY 2025 program years also use CY 2020 data, but we are not proposing to suppress the MORT-30 PN measure in the FY 2024 and FY 2025 program years at this time. We will continue to analyze this data and will address suppression of MORT-30-PN for additional program years in future rulemaking.”

SHEA supports CMS’ proposed measure suppression policy applicable to MORT-30-PN (NQF #0468) for the FY 2023 program year based on impactful, unique COVID-19 PHE circumstances.

Retention and Removal of Quality Measures

- Proposed Removal of CMS Patient Safety and Adverse Composite (CMS PSI 90) (NQF #0531) Beginning with the FY 2023 Program Year

On p. 25478, CMS states:

“We continue to consider patient safety a high priority, but because the CMS PSI 90 measure is also used in the HAC Reduction Program, we believe removing this measure from the Hospital

VBP Program will reduce the provider and clinician costs associated with tracking duplicative measures across programs.”

SHEA agrees with CMS’ proposed removal of Removal of CMS Patient Safety and Adverse Composite (CMS PSI 90) (NQF #0531) from the Hospital VBP beginning with the FY 2023 program year. We agree with CMS’ rationale regarding the measure’s proposed removal, including duplicative measure and scoring methodologies across programs. Of note, however, the measure is retained in the HAC Reduction Program (with the exception of measure suppression for Q3 and Q4 of 2020) and should be retained in the HAC Reduction Program.

- Updates to the Specifications of Four Condition-Specific Mortality Measures and One Procedure-Specific Complication Measure Beginning with the FY 2023 Program Year to Exclude Patients Diagnosed with COVID-19

On p. 25479, CMS states:

“We are updating the following four condition-specific mortality measures and one procedure-specific complication measure to exclude patients with either principal or secondary diagnoses of COVID-19 from the measure denominators beginning with the FY 2023 program year.

- *Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230)*
- *Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558)*
- *Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1893)*
- *Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate Following Heart Failure Hospitalization (NQF #0229)*
- *Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550)”*

Consistent with reasoning cited above, SHEA agrees with CMS’ proposal to exclude patients with either principal or secondary diagnoses of COVID-19 from the above-referenced condition-specific mortality and procedure-specific complication measure denominators beginning with the FY 2023 program year.

Previously Adopted Baseline and Performance Periods

- Proposal to Update the Baseline Periods for Certain Measures due to the Extraordinary Circumstances Exception Granted in Response to the COVID-19 PHE

On p. 25483, CMS proposes updates to the baseline periods for various measure domains (e.g., Person and Community Engagement Domain), noting e.g.:

“...[W]e believe using four consecutive quarters of data for the baseline period will provide a higher level of data accuracy and reliability for scoring hospitals on the HCAHPS Survey.”

SHEA agrees with CMS’ logic regarding the inclusion of full-year 2020 data (including Q3 and Q4 2020 data) for the baseline period for the FY 2024 program year for the measure domains delineated in the rule. The inclusion of four consecutive quarters of data in the baseline will yield higher accuracy and reliability relative to scoring hospitals on these domains.

Performance Standards for the Hospital VBP Program

- Previously Established and Estimated Performance Standards for the FY 2024 Program Year

On p. 25489, CMS states:

“As discussed in section V.H.4.b. of the preamble of this proposed rule, we are proposing to update the FY 2024 program year baseline periods for the measures included in the Safety, Person and Community Engagement, and Efficiency and Cost Reduction domains. If finalized, according to our established methodology for calculating performance standards, we will use data from January 1, 2019 through December 31, 2019 to calculate performance standards for the FY 2024 program year for these measures.”

SHEA suggests CMS assess the reliability and validity of using FY2019 baseline rates for future year value-based purchasing programs. The changes to healthcare delivery as outlined throughout this proposed rule are pervasive in their impact on patients with COVID-19 and those without and are unlikely to be completely adjusted by simply removing COVID-19 positive patients.

Scoring Methodology and Data Requirements

- Proposed Scoring Methodology for the FY 2022 Program Year Due to the PHE for COVID-19

On p. 25493, CMS states:

“In order to ensure that hospitals are aware of changes in their performance rates that we have observed, we are proposing to provide FY 2022 confidential feedback reports that contain the measure rates we have calculated for the FY 2022 program year, along with achievement and improvement scores for the measures in the Clinical Outcomes Domain and a Clinical Outcomes Domain score. However, as previously discussed, we are proposing that the measure rates and Clinical Outcome Domain performance scores would not be used to calculate TPSs [Total Performance Scores] for the purpose of adjusting hospital payments under the FY 2022 Hospital VBP Program.”

SHEA supports CMS’ proposal to provide ongoing confidential feedback reports to hospitals regarding their performance on the aforementioned measure domains but to not include for purposes of calculating the TPS.

- Overall Hospital Quality Star Ratings

On p. 25495, citing its CY 2021 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) final rule with comment period and interim final rule with comment period, CMS reiterates the intention of the Overall Star Ratings, noting:

“The Overall Star Ratings utilize data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the Hospital VBP Program.”

SHEA reiterates its support for CMS’ development of Overall Star Ratings as a method by which to publicly convey hospital performance information in a more usable and interpretable way.

Hospital-Acquired Conditions (HAC) Reduction Program

Proposed Flexibility for Changes That Affect Quality Measures During a Performance or Measurement Period in the HAC Reduction Program

- Cross-Program Measure Suppression Policy Proposal (Applicable to HRRP, Hospital VBP, HAC Reduction Program and Other Value-Based Purchasing Programs) for Duration of COVID-19 PHE

Please refer to SHEA’s comments regarding this broader CMS proposal in the HRRP section of our comment letter. SHEA maintains that those facilities requiring measure suppression not have a Total HAC Score calculated. Doing so could inadvertently skew toward rewarding these facilities when compared to facilities whose data was not suppressed. Moreover, this process could add a layer of subjectivity relative to CMS’ determination of whether certain outlier data is attributed to the COVID-19 PHE versus data that is not attributed to the PHE.

- Proposal to Suppress Third and Fourth Quarter CY 2020 Data from the FY 2022 and FY 2023 HAC Reduction Program

On p. 25499, CMS states:

“ We are proposing to suppress the third and fourth quarters of CY 2020 (that is, July 1, 2020 through September 30, 2020 (Q3 2020) and October 1, 2020 through December 31, 2020 (Q4 2020)) CDC NHSN HAI and CMS PSI 90 data from our performance calculations for FY 2022 and FY 2023 under the proposed Measure Suppression Factor (1)...Although Q3 and Q4 2020 data would be suppressed from the Total HAC Score calculation, hospitals would still be required to submit such data and such data would be used for public reporting purposes....”

SHEA supports suppressing Q3 and Q4 of CY 2020 CDC NHSN HAI and CMS PSI 90 data from the Total HAC Score calculation for FY 2022 and FY 2023. However, we have concerns regarding CMS’ resulting proposed periods for calculating Total HAC Scores for the FY 2022 and FY 2023 HAC Reduction Program. CMS’ proposed inclusion of data spanning January 1, 2021 through June 30, 2020 data, e.g., may be problematic, given that the COVID-19 PHE was (and still is) ongoing.

Hospital Inpatient Quality Reporting (IQR) Program

Proposals to Adopt New Measures for the Hospital IQR Program Measure Set

- Proposed Maternal Morbidity Structural Measure affecting FY 2023 payment determination

On page 1265, CMS states:

Therefore, in this proposed rule, we are proposing to adopt the Maternal Morbidity Structural Measure (Maternal Morbidity measure), beginning with a shortened reporting period running from October 1, 2021 through December 31, 2021, affecting the FY 2023 payment determination, to help address this maternal health crisis. After which, the reporting period would be 12 months beginning with the FY 2024 payment determination (reporting period January 1, 2022 through December 31, 2022) and for subsequent years. We developed this structural measure to determine hospital participation in a State or national Perinatal Quality Improvement (QI) Collaborative initiative and implementation of patient safety practices or bundles within that QI initiative. We define a state or national Perinatal Quality Improvement Collaborative as a statewide or a multi-State network working to improve women’s health and maternal health outcomes by addressing the quality and safety of maternity care.

SHEA supports the adoption of the Maternal Morbidity Structural Measure for the Hospital IQR Program. We agree with CMS that “this measure would be the first step” in addressing maternal mortality. **We also urge CMS to consider adopting a measure that tracks surgical site infections (SSIs) associated with a cesarean section (C-section).** SSI is a common complication of C-sections, with a reported incidence rate of 3 to 15 percent among women who undergo C-sections and a mortality rate of up to 3 percent.¹ Research shows that women of color and low-income women are more likely to have risk factors of post-cesarean SSI and more likely to have a C-section delivery than other demographics.²

SHEA also supports the adoption of a measure of other complications associated with a C-section, such as a hysterectomy within 30 days of a C-section. Women with C-sections are almost four times more likely to have complications requiring a hysterectomy than women with vaginal delivery, and the mortality rate from peripartum hysterectomy is 25 times greater than that of non-obstetric hysterectomy.^{3,4} Women of color experience higher rates of peripartum hysterectomy and associated mortality than white women.⁵

The National Healthcare Safety Network (NHSN) allows participating hospitals to track SSI events specific to operative procedures, including those associated with C-sections with the category code CSEC and those associated with abdominal hysterectomies with code HYST.⁶

- Proposed Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) Measure affecting FY 2026 payment determination

¹ <https://dx.doi.org/10.2147%2FIJWH.S98876>

² <https://pqnc-documents.s3.amazonaws.com/sivbIIIIdoc/POCNCsIVBIIIUnequal20121028.pdf>

³ <https://doi.org/10.1186/s12884-018-1829-7>

⁴ <https://dx.doi.org/10.1097/AOG.0b013e3181df94fb>

⁵ <https://doi.org/10.1002/ijgo.13304>

⁶ <https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscscscurrent.pdf>

On page 1274, CMS states:

Condition-specific mortality measures previously adopted into the Hospital IQR and Hospital VBP Programs support quality improvement work targeted toward patients with a set of common medical conditions, such as stroke, heart failure, acute myocardial infarction, or pneumonia. Following the implementation of condition-specific measures, national hospital mortality rates for the measured conditions and/or procedures have declined. Now, we are interested in also measuring hospital performance across a broader set of patients and across more areas of the hospital. We developed a hybrid hospital-wide, all-cause, risk-standardized mortality measure that uses claims data to define the measure cohort and a combination of data from electronic health records (EHRs) and claims for risk adjustment (Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (hereinafter referred to as the “Hybrid HWM measure”)).

SHEA supports the adoption of the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) Measure for the Hospital IQR Program. We applaud CMS’ efforts to bolster hospital-wide quality measurement, as it will help drive quality improvement and promote effective treatment to reduce risk-adjusted mortality across all hospitals, including low-volume hospitals whose performance is not captured in condition- or procedure-specific mortality measures. SHEA appreciates the alignment between the Hybrid HWM Measure and the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data, as this will ease implementation for hospitals. Additionally, we agree that starting with a voluntary reporting period (July 1, 2022 through June 30, 2023) before requiring data submission would provide hospitals sufficient time to test the extraction of the core clinical data elements from electronic health records.

- Proposed Hospital Harm-Severe Hypoglycemia eCQM affecting FY 2025 payment determination

On page 1306, CMS states:

To address gaps in measurement, we developed the Hospital Harm—Severe Hypoglycemia eCQM, an outcome measure that would identify the rates of severe hypoglycemic events using direct extraction of structured data from the EHR. We believe this measure will provide reliable and timely measurement of the rate at which severe hypoglycemia events occur in the setting of hospital administration of antihyperglycemic medications during hospitalization, which will create transparency for providers and patients with respect to variation in rates of these events among hospitals. We believe that adopting this measure, which focuses on in-hospital severe hypoglycemic events in the setting of hospital-administered antihyperglycemic medications, has the potential to reduce preventable harm. Therefore, we are proposing to adopt the Hospital Harm—Severe Hypoglycemia eCQM (NQF #3503e) beginning with the CY 2023 reporting period/FY 2025 payment determination.

SHEA supports the adoption of the Hospital Harm-Severe Hypoglycemia eCQM. Hypoglycemia is associated with prolonged hospital stay, which may predispose patients to increased risk of healthcare-associated infections and other complications.⁷ Glucose management in hospitalized patients is a critical infection control strategy.

⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4794639/>

- Proposed Hospital Harm-Severe Hyperglycemia eCQM affecting FY 2025 payment determination

On page 1314, CMS states:

We believe that this proposed measure, which focuses specifically on severe hyperglycemic events in the hospital setting, has the potential to reduce preventable harm. Therefore, we are proposing to adopt the Hospital Harm—Severe Hyperglycemia eCQM (NQF # 3533e) beginning with the CY 2023 reporting period/FY 2025 payment determination.

While SHEA supports the intent of the Hospital Harm-Severe Hyperglycemia eCQM, we recommend that CMS revise the numerator criteria to encompass glycemic control more comprehensively. As proposed, the Hospital Harm-Severe Hyperglycemia eCQM does not capture a hyperglycemic event that occurs during “the first 24-hour period after hospital arrival for admitted patients (including the emergency department)” in the numerator, therefore excluding patients with poor glycemic control. Diabetes, beyond its association with hyperglycemia, is a significant risk factor for surgical site infections in various types of surgeries, including arthroplasty, breast, cardiac, and spinal surgeries.⁸ SHEA urges CMS to instead use a hemoglobin A1c test as the measure because it reflects a three-month average for glycemic control.

Future Considerations

- Potential Future Development and Inclusion of a 30-Day, All-Cause Mortality Measure for Patients Admitted With COVID-19 Infection

On page 1331, CMS states:

We are working to learn more about the impact of the COVID-19 infection on measure outcomes, particularly readmission and mortality measures, and about how the burden of the PHE for COVID-19 influences hospitals’ ability to care for patients. To support our efforts, we are considering the potential future inclusion of a new hospital-level measure of all-cause mortality for Medicare beneficiaries admitted with COVID-19 infection (COVID-19 mortality measure).

SHEA generally supports the intent of the development and inclusion of a 30-Day, All-Cause Mortality Measure for Patients Admitted With COVID-19 Infection. However, we are concerned that such a measure could penalize hospitals that predominantly care for disadvantaged populations. As CMS pursues development of this important measure, we urge CMS to follow the National Quality Forum’s recommendation to adjust for social risk factors only when conceptual and empirical evidence supports its inclusion.⁹ With regard to specific social risk factors, SHEA recommends CMS examine social drivers of access to health care, such as transportation and working conditions.

- Potential Future Efforts to Address Health Equity in the Hospital IQR Program

On page 1345, CMS states:

⁸ <https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/diabetes-and-risk-of-surgical-site-infection-a-systematic-review-and-metaanalysis/32E3729E4CF28827E591C41A9914B398>

⁹ https://www.qualityforum.org/Publications/2017/07/Social_Risk_Trial_Final_Report.aspx

We are seeking comment on potentially expanding our efforts to provide results of the Within- and Across-Hospital Disparity Methods to promote health equity and improve healthcare quality. Specifically, we are seeking comment on the idea of stratifying the performance results of the Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF# 1789) by dual eligibility and indirectly estimated race and ethnicity, as described in section IX.B. of the preamble of this proposed rule. We also seek comment on the idea of stratifying said performance results by disability status and seek suggestions for appropriate measures of disability status that could be derived from administrative data or self-reporting for this purpose. Results would be presented if technically feasible, adequately representative, and statistically reliable.

SHEA commends CMS’ efforts to advance racial equity and support underserved communities through the Hospital IQR Program. We support stratifying the performance results of the Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure by race and ethnicity, dual eligibility status, and disability status, as this level of granularity is needed to implement quality improvement interventions tailored specifically to these populations.

SHEA agrees with CMS’ rationale to begin with confidential, hospital-specific reports before publicly reporting stratified results. The availability of this data will provide hospitals with the information necessary to evaluate the effectiveness of quality improvement strategies in reducing health disparities and to inform the development of more targeted interventions.

Additional Comments

SHEA recommends revisions to the Severe Sepsis and Septic Shock Early Management Bundle (SEP-1) aimed at achieving a better balance between immediate antibiotic treatment for patients in need of such treatment and limiting antibiotic overuse. We are concerned that SEP-1, as stipulated, compels a “one-size-fits-all” approach for treating all patients with possible sepsis risk that can drive antibiotic overuse and contribute to the antibiotic resistance crisis. SHEA recommends the elimination of “sepsis without shock” from SEP-1 due to the dearth of evidence on the impact of antibiotics on survival for sepsis without shock and limiting SEP-1 to septic shock alone. To be clear, this recommendation intends to mitigate the risk of indiscriminately administering antibiotics to patients who present with signs and symptoms resembling sepsis. Removing “septic without shock” from SEP-1 will allow clinicians to make an individual clinical determination based on the varied patient factors without the pressure to follow a single treatment pathway. Additional recommendations are outlined in “Infectious Diseases Society of America Position Paper: Recommended Revisions to the National Severe Sepsis and Septic Shock Early Management Bundle (SEP-1) Sepsis Quality Measure.”¹⁰

Proposed COVID-19 Vaccination Coverage Among HCP Measure Affecting FY 2023 payment Determination in Hospital IQR Program, PCHQR Program, and LTCH QRP Program

On page 1296, CMS states:

“We believe it is important to incentivize and track HCP vaccination in acute care facilities through quality measurement to protect health care workers, patients, and caregivers, and to help sustain the ability of hospitals to continue serving their communities throughout the PHE and beyond.

¹⁰ <https://academic.oup.com/cid/article/72/4/541/5831166>

Therefore, we are proposing a new measure, COVID-19 Vaccination Coverage Among HCP, beginning with a shortened reporting period from October 2021 through December 2021. The CY 2021 Reporting Period for the FY 2023 Payment Determination is shorter than the reporting period we are proposing for subsequent years to expedite data collection of this measure in response to the current PHE. The measure will assess the proportion of a hospital's health care workforce that has been vaccinated against COVID-19."

On page 1380, CMS states:

We believe it is important to require that PCHs report their rates of HCP vaccination in order to assess whether they are taking steps to limit the spread of COVID-19 among their HCP, and to help sustain the ability of U.S. hospitals to continue serving their communities throughout the PHE and beyond. Therefore, we are proposing a new measure, COVID-19 Vaccination Coverage Among HCP (COVID-19 vaccination measure), beginning with the FY 2023 program year. For that program year, PCHs would be required to report data on the measure for the fourth quarter of CY 2021 (that is, from October 2021 through December 2021).

On page 1398, CMS states:

We believe it is important to require that LTCHs report COVID-19 HCP vaccination in order to assess whether they are taking steps to limit the spread of COVID-19 among their HCP, reduce the risk of transmission of COVID-19 within their facilities, and to help sustain the ability of LTCHs to continue serving their communities throughout the PHE and beyond. We also believe that publishing facility-level COVID-19 HCP vaccination rates on Care Compare would be helpful to many patients, including those who are at high-risk for developing serious complications from COVID-19, as they choose facilities from which to seek treatment. Under the Meaningful Measures framework, the COVID-19 Vaccination Coverage among Healthcare Personnel measure addresses the quality priority of "Promote Effective Prevention & Treatment of Chronic Disease" through the Meaningful Measures Area of "Preventive Care." Therefore, we are proposing a new measure, COVID-19 Vaccination Coverage among HCP to assess the proportion of an LTCH's healthcare workforce that has been vaccinated against COVID-19.

As expressed in a recent policy statement, SHEA believes that all health care personnel (HCP) should be immunized pursuant to the Centers for Disease Control and Prevention (CDC) and Advisory Committee on Immunization Practices (ACIP) recommendations and that only medical contraindications should be accepted as a reason for not receiving such vaccinations.¹¹

During the MUC review process, SHEA expressed concern regarding the potential implications of the measure's inclusion in CMS quality programs given the early (at the time of our January 2021 comments) stage at which the vaccines were in the FDA approval process. In our comments, SHEA also raised concerns regarding the safety of the vaccine use in certain populations (e.g., pregnant women and

¹¹ <https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/policy-statement-from-the-society-for-healthcare-epidemiology-of-america-shea-only-medical-contraindications-should-be-accepted-as-a-reason-for-not-receiving-all-routine-immunizations-as-recommended-by-the-centers-for-disease-control-and-prevention/C002ADE2C91FC6113268258DB27954DD>

immunocompromised individuals) and considerations regarding the mandate of an Emergency Use Authorization (EUA)-authorized vaccine.

While those concerns remain, SHEA is encouraged by the CDC's measure validity testing follow the MUC formal comment period earlier this year and the measure specifications subsequently delineated by the CDC in March 2021.¹² Given the measure's potential to generate actionable data on vaccination rates, we encourage CMS, in collaboration with the CDC, to continue to hone the measure as it is submitted for NQF endorsement in the future.

Closing the Health Equity Gap in CMS Hospital Quality Programs – Request For Information

On page 1259, CMS states:

We are currently seeking comment on the possibility of expanding our current disparities methods to include reporting by race and ethnicity using indirect estimation. We are also seeking comment on the possibility of hospital collection of standardized demographic information for the purposes of potentially incorporating into measure specifications to permit more robust equity measurement. Additionally, we are seeking comment on the design of a Hospital Equity Score for calculating results across multiple social risk factors and measures, including race/ethnicity and dual eligibility.

While attention on health care equity has increased, considerable knowledge gaps on racial and ethnic disparities in healthcare-associated infections still exist, limiting the ability to apply targeted infection control and prevention interventions.¹³ A retrospective analysis of the U.S. National Hospital Discharge Surveys from 2001 to 2010 found that Black patients had significantly higher mortality and risk for severe *Clostridium difficile* infection (CDI), despite a higher incidence of CDI among white patients.¹⁴ Another study using data from the Medicare Patient Safety Monitoring System (MPSMS) found significantly higher rates of healthcare-associated infection among Asian and Hispanic patients than white non-Hispanic patients.¹⁵

We recommend CMS consider collecting process measures relevant to infection control and prevention, along with antibiotic stewardship, and stratifying data by patient demographic characteristics to detect and respond to differences in quality. Quality measurement may help monitor compliance with infection control policies and identify areas for improvement in targeted infection control practices. Well-documented process measures include, for example, “observation of hand hygiene compliance, observation of correct catheter care technique, antibiotic utilization studies, timeliness in administering and reading TB skin tests, and administration of hepatitis B immunization to new employees within 10 working days of hire.”¹⁶ The collection of infection control process measures aligns with the use

¹² <https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpccoverage-508.pdf>

¹³ [https://www.ajicjournal.org/article/S0196-6553\(15\)00880-9/fulltext](https://www.ajicjournal.org/article/S0196-6553(15)00880-9/fulltext)

¹⁴ <https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-016-1788-4>

¹⁵ <https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/racial-and-ethnic-disparities-in-healthcare-associated-infections-in-the-united-states-20092011/46847DCE9DA6AFFE5BA18D563F865730>

¹⁶ Smith PW, Bennett G, Bradley S, Drinka P, Lautenbach E, Marx J, Mody L, Nicolle L, Stevenson K. SHEA/APIC Guideline: Infection Prevention and Control in the Long-Term Care Facility. *Infect Control Hosp Epidemiol.* 2008;29(9) 785-814. doi: 10.1086/592416

of “disparities-sensitive” measures promoted in the National Quality Forum’s report, “A Roadmap for Promoting Health Equity and Eliminating Disparities: The Four I’s for Health Equity.”¹⁷

Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs – Request for Information (RFI)

On p. 25549, CMS states:

“We aim to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. As part of this modernization of our quality measurement enterprise, we are issuing this request for information (RFI). The purpose of this RFI is to gather broad public input solely for planning purposes for our transition to digital quality measurement. Any updates to specific program requirements related to providing data for quality measurement and reporting provisions would be addressed through future rulemaking, as necessary.”

SHEA commends CMS for its proposed shift toward fully digitized quality measurement in CMS quality reporting programs and VBPs by 2025. With respect to CMS’ proposed creation of a hospital equity score, modeled off the Health Equity Summary Score (HESS) used in the Medicare Advantage (MA) program, SHEA strongly supports CMS’ work in this area. We are encouraged by the multitude of social risk factors CMS is considering, including race/ethnicity and dual-eligibility, and look forward to partnering with CMS to advance policy solutions that support our joint health equity goals.

Conclusion

SHEA thanks CMS again for the opportunity to provide feedback on the IRF PPS proposed changes. As we noted, we would be happy to provide CMS with any additional detail or address any questions you may have as you work to finalize the rule.

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https://www.qualityforum.org/Publications/2017/09/A_Roadmap_for_Promoting_Health_Equity_and_Eliminating_Disparities__The_Four_I_s_for_Health_Equity.aspx